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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,899	12/29/2000	Frank J. Bunick	MCP-0262	9623

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EXAMINER	
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ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
05/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/752,899	BUNICK ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 8-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 8-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment and response dated 2-15-07 is acknowledged.

Claims 1-5 and

Response to Arguments

Applicant's arguments filed 2-15-07 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office actions.

Claims 1, 3-5 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,667,050 to Boissonneault et al ('050) in view of US 4,684,534 to Valentine.

'050 teach a chewable tablet composition comprising an active ingredient and carriers such as dextrose, microcrystalline cellulose, polyvinylpyrrolidone etc (all of which are claimed in the instant) and sucralose (examples). The examples of '050 contain sucralose as a sweetener. '050 teach the same binders and disintegrants that are also claimed in the instant invention but fail to teach dextrose monohydrate.

Valentine teaches a chewable tablet composition comprising excipient base materials such as carbohydrate based agglomerate materials including dextrose, dextrose monohydrate, fructose, sucrose etc., which are held together by small quantities of binding materials such as maltodextrin (col. 2-3).

The carbohydrate agglomerates are in the size range of 20 to 100 microns (col. 4, L 29-35 & col. 9, lines 20-42) and particulate active agent having a particle size of about 50 microns (col. 4).

Valentine teaches at least 25% by weight of the carbohydrate agglomerate and in particular, claim 3 recites 90% to 99% by weight for a quick melting tablet. Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made that the particulate agglomerated carbohydrates such as dextrose or dextrose monohydrate are equally effective for compressibility. A skilled artisan would have employed particulate dextrose or dextrose monohydrate in the tablet composition '050 because Valentine suggests that the carbohydrates enable the tablets to be highly compressible and also the tablets readily dissolve in minimal amounts of water in the mouth thus quickly liquefying of the active agent. With respect to the ratio of dextrose monohydrate and sucralose, one of an ordinary skill in the art would have optimized the amounts or ratios of components of the chewable tablets depending on the sweetness of the tablet desired.

RESPONSE: Instant claim 1 has been amended to recite that the active agent is present in a matrix consisting essentially of from about 15% to about 90% by weight of directly compressible dextrose monohydrate having an average particle size of about 100 to 500 microns.

Valentine teaches that the active agent is mixed with the agglomerated carbohydrate binder so as to cause the active agent to be entrained by and dispersed in the agglomerate (col. 3, L 30-35), which meets the limitation of the active agent in a matrix. Further Valentine teaches the particle sizes of carbohydrate and the active agent to be less than 300 microns (which falls within the claimed range of 100-500 microns) and 50 microns respectively; Applicants have not shown any unexpected advantage with the claimed particle sizes of the active agent. On the other hand, Valentine teaches that depending on the solubility of the active agent, one can employ a higher (for soluble) or lower (insoluble) particle sizes (col. 4, L 29-46).

Applicants' detailed arguments, all of which are not reproduced here, have been fully considered. It is argued that instant claims affirmatively require, among other things, "directly compressible" dextrose monohydrate (emphasis added) and questions as to where in the teachings of Valentine and Boissonneault such a limitation can be found. It is argued that at the most, the rejection states, "particulate agglomerated carbohydrates such as dextrose or dextrose monohydrate are equally effective for compressibility". It is argued that Valentine teaches dextrose monohydrate in a list of possible carbohydrate particles that are used to make carbohydrate-based agglomerates is not a disclosure or suggestion of directly compressible dextrose monohydrate. It is argued that Valentine requires agglomeration of carbohydrate before compressing into a tablet and is hence not directly compressible.
Applicants' arguments are not persuasive because instant claims recite "directly compressible", which is property of dextrose monohydrate that is capable of being directly compressed. Instant claims do not state that the tablet is prepared by direct compression of dextrose monohydrate. Further, instant claims do not exclude agglomeration of dextrose monohydrate before being "directly compressible". Accordingly, the process of agglomeration, followed by compression, taught by Valentine, still reads on the instant claims. While Valentine does teach dextrose monohydrate as one of the possible carbohydrates listed, the reference also discloses the compound in the examples (table A and example XIII). The chewable tablets of Valentine are prepared by direct compression, as disclosed in the Objects and summary of the invention.

Applicants argue that there is no reasonable expectation of success to use dextrose monohydrate from Valentine in Boissonneault method of dry granulation. However, the latter teaches both dry and wet granulation methods, which result in compressed tablets (see page 12 of applicants' response for the granulation techniques of Boissonneault). Both the references teach chewable tablets prepared by direct compression. With respect to the argument that the technologies employed by the references are different, instant claims do not specify any particular process of preparation, whereas the references discuss dry granulation, wet granulation as well as fluid bed technology for the same chewable tablet preparation. Applicants have not provided any comparative advantage of employed direct compression over other techniques in preparing in the instant chewable tablets.

Applicants argue that based on examiner's position of equating dextrose and dextrose monohydrate, one can equate mannitol and dextrose monohydrate of Boissonneault are considered equal. However, it is argued that the data presented in the instant application does not show that directly compressible dextrose and mannitol are not equally effective. However, instant rejection provides a motivation to incorporate dextrose monohydrate in place of dextrose. The combination does not suggest incorporating mannitol. Accordingly, the results discussed in the instant specification are

not pertinent. However, a proper comparison would be to show unexpected advantage of dextrose monohydrate in the claimed compositions over dextrose, prepared by the instant method.

In response to applicants' statement that the instant application and US 6,270,790 were commonly owned by or subject to an obligation of assignment to the same person, the following rejection has been withdrawn.

Claims 1-5 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,270,790 ('790) to Robinson et al in view of US 4,684,534 to Valentine.

In response to the amendment, the double patenting rejection of record has been re-written as follows:

Double Patenting

Claims 1, 4-5, 8 and 10-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,814,978 ('978) in view of US 6,270,790 ('790) and US 4,684,534 to Valentine.

'978 claim a chewable tablet composition comprising dextrose monohydrate and a pharmaceutically active ingredient. The dependent claims of '978 include the same active excipients claimed I the instant invention. Patented claims do not require fat and also lacks non-saccharide water-soluble polymers. Crospovidone of the patented claims is a cross-linked polyvinylpyrrolidone that is not water-soluble. The patented

composition does not contain sucralose of instant claims. The patented claims also fail to recite the particle size of dextrose monohydrate.

'790 teach chewable tablet compositions comprising an active ingredient, a compressible carbohydrate, sweetener, flavor and other customary ingredients (table in col. 5). Among the sweeteners, '790 teach sucralose (col. 5, lines 13-21).

Valentine, discussed above (see rejection of claims under 35 USC 103(a), teaches dextrose monohydrate particles having a particle size of less than 300 microns (col. 4, L 29-35) in chewable oral tablets. The active agents discussed by Valentine include antacids, analgesics etc (abstract and examples), which are the same as claimed in the instant invention.

Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include sweeteners such as sucralose in the chewable tablet compositions of '978 because '790 teach the above sweeteners as customary additives imparting taste to the tablets. Accordingly, a skilled artisan would have included an optimum amount of sucralose depending on the desired sweetness of the tablet. Further, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ particulate dextrose monohydrate in the composition of the patented claims because Valentine suggests particulate dextrose monohydrate for a quick liquefying chewable tablet that melts in the mouth without perceivable grit upon chewing.

Examiner notes that Applicants have neither filed a terminal disclaimer nor presented any arguments regarding this rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Au 1615
May 10, 2007

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER